

NEIFELD REF.: TACT0001

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Application No. : 09/666,068 Confirmation No. 6420

Patent No. : 6,379,666 Issued April 30, 2002

Applicant : Edward L. Tobinick

Filed : 12/11/2000

TC/A.U. : 1614

Examiner : Jarvis, William R. A.

37 CFR 1.323 REQUEST FOR CERTIFICATE OF CORRECTION
OF APPLICANT'S MISTAKE

HONORABLE COMMISSIONER OF PATENTS & TRADEMARKS
ALEXANDRIA, VA 22313

SIR:

The following is a request for a certificate of correction in Serial Number 09/666,068, now Patent Number 6,379,666. A certificate of correction under 35 USC 255 is respectfully requested in the above-identified patent.

At least one error is the fault of the applicant, and, accordingly, \$100.00 is submitted to pay the fee for a Certificate of Corrections (35 USC 255 and 37 CFR 1.323). The errors are minor and their correction would not entail re-examination or constitute new matter, and are readily apparent from the USPTO file histories, attached, and explained below.

The requested corrections are below on Form PTO 1050.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,379,666

ISSUED : April 30, 2002

INVENTORS(S) : Edward L. Tobinick

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 1, lines 6 - 10, please delete the following paragraph:

"This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."

and insert therefore:

-- This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Serial No. 09/275,070, filed March 23, 1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned. --

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION (CONTINUED)

On the front page of the patent, please delete the following paragraph:

"Divisional of application No. 09/476,643, filed on Dec. 31, 1999, now Pat No. 6,177,077, which is a continuation-in-part of application No. 09/256,388, filed on Feb. 24, 1999, now abandoned."

and insert therefore:

-- This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Serial No. 09/275,070, filed March 23, 1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned. --

MAILING ADDRESS OF SENDER:

PATENT NO. 6,379,666

No. of additional copies: 0

Neifeld IP Law, PC
4813-B Eisenhower Avenue
Alexandria, Virginia 22304

I. STATEMENT OF THE RELIEF REQUESTED

The applicant requests entry in this issued application of a Certificate of Correction that corrects the benefit claim under 35 U.S.C. §120.

The chain of priority in 09/666,068 is missing a reference to application 09/275,070. As explained below, the priority chain should refer to 09/275,070 between 09/476,643 and 09/256,388, and it should specify that 09/476,643 is a continuation-in-part of 09/275,070.

In an amendment submitted herewith, page 1 of the specification (the paragraph starting with "RELATED APPLICATIONS") is amended as follows (marked-up):

This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Serial No. 09/275,070, filed March 23, 1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned.

II. MATERIAL FACTS

A. CHAIN OF APPLICATION FILINGS

1. On February 24, 1999, the applicant filed Serial No. 09/256,388, with an original U.S. inventor declaration.

2. On September 16, 1999, applicant filed a notice of express abandonment that stated:

"Re: S.N. 09/256,388 Applicant hereby abandons the above-identified application in favor of Appln. S.N. 09/275,070, which has been allowed by Examiner Jarvis."

3. Serial No. 09/275,070 was filed on March 23, 1999, and matured into U.S. 6,015,557 on January 18, 2000. The applicant filed an original U.S. inventor declaration in 09/275,070, which specifically referred to S.N. 09/256,388.

4. Applicant filed Serial No. 09/476,643 on December 31, 1999, which is prior to January 18, 2000, and was therefore co-pending with S.N. 09/275,070. Applicant filed an original U.S. inventor declaration attached to the specification in 09/476,643 that did not refer to any prior applications.

5. Page 1 of the '643 specification, under the heading "RELATED APPLICATION" stated erroneously that "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999." This statement is erroneous because 09/256,388 had been expressly abandoned on September 16, 1999 (before the '643 application was filed) in favor of 09/275,070 which was

still pending when the '643 application was filed.

6. On July 21, 2000, applicant filed a "new" (i.e, a second) original U.S. inventor declaration in 09/476,643 that specifically refers to 09/256,388 and to 09/275,070, thus correcting priority and preserving co-pendency throughout all applications in the chain.

7. Serial No. 09/476,643 matured into U.S. 6,177,077 on January 23, 2001. On page 1 of the patent specification, as amended on July 21, 2000, it states "This application is a continuation-in-part of Ser. No. 09/275,070, filed March 23, 1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."

7. Applicant first filed the subject divisional (Ser. No. 09/666,068) on September 19, 2000, but later was accorded an official filing date of December 11, 2000, which however is still prior to January 23, 2001. Thus divisional 09/666,068 was co-pending with its parent application 09/476,643. The applicant filed the same inventive specification, a copy of the U.S. inventor declaration from 09/476,643, and relied upon that copy of the original inventor declaration to secure the December 11, 2000 filing date.

8. On 12/06/2000, applicant filed a request for Correction of Filing Receipt stating erroneously: "THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999, WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED." This statement is erroneous because 09/476,643 is actually a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part of 09/256,388, due to lack of co-pendency, as explained above.

9. On 11/15/2001, the Related Application statement on page 1 of subject application 09/666,068 was amended by the Examiner (as indicated by handwritten, dated initials) to add the following underlined text: "This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." This statement is erroneous because 09/476,643 is actually a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part of 09/256,388, due to lack of co-pendency, as explained above.

11. On 02/22/2001, an Official Filing Receipt was issued in 09/666,068 stating "THIS APPLICATION IS A DIV OF 09/476,643, 12/31/1999, PAT 6,177,077 WHICH IS A CIP OF 09/256,388, 2/24/1999, ABANDONED." This statement is erroneous because 09/476,643 is in fact a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part. 09/256,388, due

to lack of co-pendency, as explained above.

12. So in 09/666,068, the applicant's request for Correction of Filing Receipt (12/06/2000), the Examiner's amendment to the specification (11/15/2001), and the Official Filing Receipt (03/22/2001) are all incorrect. That is because 09/476,643 is actually a continuation-in-part of Serial No. 09/275,070, while 09/275,070 is a CIP of 09/256,388.

13. As a result of these facts the 09/666,068 application contains an erroneous priority chain.

B. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/666,068

14. Exhibit 1 is a copy of the 2 page transmittal letter, and page 1 of the specification filed on 09/19/2000 in application 09/666,068. The upper left hand corner of Exhibit 1 has a USPTO date stamp showing "09/19/00" The upper right hand corner shows the USPTO application number "09/666,068."

15. Exhibit 1, pages 1 and 2, indicate that 09/666,068 was filed as a Rule 60 divisional incorporating the prior specification and inventor declaration. Item 8 is checked, and amends the specification before the first line to recite "division of application number 09/476,643, filed Dec. 31, 1999."

16. Exhibit 1 page 3 shows the original first sentence of the specification, i.e., "This is a continuation-in-part of application Serial No. 09/256,388, filed on February 24, 1999" along with the Examiner's handwritten amendment dated 11/15/2001, revising the priority claim to recite "This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." (marked-up)

17. Exhibit 2, pages 1 and 2 shows the applicant filed a copy of the original U.S. inventor declaration from 09/476,643, signed by Edward L. Tobinick, M.D. on December 29, 1999, and relied upon that copy to secure the December 11, 2000 filing date.

18. Exhibit 2, page 3 shows applicant requested a correction of filing receipt, dated-stamped "12/06/2000," in stating erroneously: "THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999, WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED."

19. Exhibit 3, pages 3 - 4 show a two page transmittal letter, date-stamped "Dec 11, 2000" filed in response to the Notice to File Missing Parts, listing "A copy of the Declaration from the parent application (U.S. Serial No. 09/476,643)".

20. Exhibit 3, pages 1 is a Official Filing Receipt mailed "01/24/2001." Exhibit 3, page 2 is an Official Filing Receipt mailed "02/22/2001."
21. Application 09/666,068 issued as USP 6,379,666.
22. Exhibit 4 is a printout of the first two columns of USP 6,379,666.
23. Exhibit 4 shows that the first sentence of USP 6,379,666 recites "This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."
24. **The foregoing facts show that the USPTO records show that application 09/666,068 is a divisional of 09/476,643.**

C. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/476,643

25. Exhibit 5, pages 1 and 2 shows the original inventor declaration from application 09/476,643, signed by Edward L. Tobinick, M.D., on December 29, 1999. Exhibit 5, page 3 is the first page of the PTO file history for application 09/476,643, stating in the examiner's handwriting verification that "THIS APPLN is a CIP OF 09/275,070 03/23/99 PAT 6,015,557 WHICH IS A CIP OF 09/256,388 02/24/99 ABN"
26. Exhibit 6, page 1 is a one page transmittal letter dated "December 31, 1999 BY EXPRESS MAIL" for a new application showing the filing of an original inventor's declaration. At the upper left is the date "12/31/99" and at the upper right is the serial number "09/476643". Exhibit 6, page 2 shows the first page of the specification, which one can see originally said "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999." This sentence was crossed-out by the examiner.
27. Exhibit 7, page 1 is the first page of the PTO File History, amended in handwriting by the examiner to state "This Appln is a CIP OF 09/275,070 PAT #6,015,557 WHICH IS A CIP OF 09/256,388 02/24/99 ABN." Exhibit 7, page 2 is another copy of the one page transmittal letter dated "December 31, 1999 BY EXPRESS MAIL" for a new application showing the filing of an original inventor's declaration. At the upper left is the date "12/31/99" and at the upper right is the serial number "09/476643". Exhibit 7, page 3 is an inventor declaration filed with the application. Exhibit 7, page 4 shows the first page of the specification as filed, which stated "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999". This sentence was later crossed-out by the examiner.

28 Exhibit 8, page 1 is a Terminal Disclaimer over US 6,015,557, and page 2 is an original inventor declaration claiming benefit of application "09/275,070 March 23, 1999 U.S. Patent No. 6,015,557" and "09/256,388 February 24, 1999 Abandoned"

29 Exhibit 9, page 2 shows the handwritten amendment by the examiner, dated 8/24/2000 changing the first sentence of the specification to recite "This application is a continuation-in-part of Application Serial No. 09/275,070, filed on March 23, 1999, now U.S. Patent 6,015,557, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on February 24, 1999, now abandoned"

30. Exhibit 10 is a printout of the first two columns of US 6,177,077, stating in the first paragraph that "This application is a continuation-in-part of Application Serial No. 09/275,070, filed on Mar 23, 1999, now U.S. Pat. No. 6,015,557, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."

31. **The foregoing facts show that the USPTO records show that application 09/476,643 was a continuation-in-part of 09/275,070.**

D. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/275,070

32. Exhibit 11, page 1 is a transmittal letter dated "March 23, 1999 BY EXPRESS MAIL." Page 2 is the first page of the specification as filed.. Pages 3 and 4 are a copy of the original inventor declaration, claiming benefit under 35 USC 120 to "09/256,388 24 February 1999 pending" signed on 3-20-99 by two inventors, Dr. Edward L. Tobinick, and Arthur Jerome Tobinick. Pages 5 -8 are a copy of a Petition to Make Special filed March 23, 1999. At the upper right on page 5 is the serial number "09/257070" and the date "03/23/99".

33. Exhibit 12 is a printout of the first two columns of US 6,015,557, stating in the first paragraph that "This application is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."

34. **The foregoing facts show that the USPTO records show that application 09/275,070 was a continuation-in-part of 09/256,388.**

E. USPTO RECORDS SHOWING THE FILING DATE OF 09/256,388

35. Exhibit 13, page 3 is a copy of the first page USPTO file history for application 09/256,388, showing "FILING DATE 02/24/99." Pages 1 - 2 show the original inventor declaration, dated

February 21, 1999, signed by two inventors, Dr. Edward L. Tobinick, and Arthur Jerome Tobinick. In 09/256,388, inventor "Edward L. Tobinick, M.D." is the same person as "Dr. Edward L. Tobinick" in 09/275,070 (and "Edward L. Tobinick, M.D." in 09/476,643).

36. Exhibit 14 is another copy of the inventor declaration. Page 2 is transmittal letter dated "FEBRUARY 24, 1999 BY EXPRESS MAIL" listing the filing of an inventor declaration, and specification. Page 3 of Exhibit 14 is the first page of the specification as filed.

37. Exhibit 15, pages 1 - 2 is a Notice of Abandonment "mailed 09/27/99." Exhibit 15, page 3 is communication by applicant dated 9/16/99 stating: "Re: S.N. 09/256,388 Applicant hereby abandons the above-identified application in favor of Appln. S.N. 09/275,070, which has been allowed by Examiner Jarvis."

38. **The foregoing show that the USPTO records show that application 09/256,388 was filed on February 24, 1999 and abandoned on Sept. 16, 1999.**

F. FACTS WHY THE REQUESTED RELIEF IS NOT MOOT

39. Pending Tobinick application 12/714,205 claims priority to 09/666,068 as "a continuation of application Serial No. 11/262,528, filed on Oct. 28, 2005, which is a division of application Ser. No. 10/269,745, filed Oct. 9, 2002, now U.S. Pat. No. 6,982,089, which is a continuation-in-part of application Ser. No. 09/841,844, filed on Apr. 25, 2001, now U.S. Pat. No. 6,537,549, which is a continuation-in-part of application Ser. No. 09/826,976, filed on Apr. 5, 2001, now U.S. Pat. No. 6,419,944, which is a continuation-in-part of application Ser. No. 09/666,068, filed Dec. 11, 2000, now U.S. Pat. No. 6,379,666, which is a division of application Ser. No. 09/476,643, filed on Dec. 31, 1999, now U.S. Pat. No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/275,070, filed on Mar. 23, 1999, now U.S. Pat. No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." (emphasis added)

G. FACTS SHOWING THE FAILURE TO PROPERLY CLAIM BENEFIT WAS UNINTENTIONAL

40. The foregoing facts 1 - 39 show that failure to claim in this application priority to 09/666,068 was an unintentional clerical error.

H. FACTS RELATING TO THE LEGAL STANDARD FOR ENTRY OF CORRECTION OF BENEFIT CLAIMS

41 Exhibit 16 is a copy of pages from Section 1481.03 of the current version of the MPEP.

I. RELATED USPTO PROCEEDINGS

42. The applicant is presenting herewith an Amendment to correct benefit in prior application 09/666,068.

43. The applicant is filing herewith a corresponding request for a certificate of correction in the patent that issued from this application, U.S. Pat. 6,379,666.

III. REASONS WHY THE PETITION SHOULD BE GRANTED

On the merits, the petition should be granted because (1) the relief requested is not moot; (2) an amendment as to benefit in an issued application is submitted herewith, (3) all of the elements required under 37 CFR 1.78(a)(3) have been presented, so awarding a corrected priority chain in application Ser. No. 09/666,068 is proper, and (4) a request for the appropriate Certificate of Correction has been filed.

A. STANDARD FOR GRANT OF PETITION

1. FORMAL MATTERS

The petition filed herewith requests entry of an amendment in an issued application filed after November 29, 2000. Therefore petition under Rule 1.78 is proper.

(CX13 "Eighteen-Month Publication Questions and Answers"
<http://www.uspto.gov/patents/law/aipa/18month/18monthfaq.jsp#cx>)

The applicant is paying the 37 CFR 1.17(t) fee therefore via credit card upon EFS web submission of the petition.

2. THE PETITION IS NOT MOOT

The petition is not moot because, even though 09/666,068 is issued, a pending application claims priority to this application. Fact 39.

3. CRITERIA FOR CORRECTION OF BENEFIT

The amendment and accompanying petition is to correct benefit. The requirements to obtain benefit and to correct benefit are governed by Rule 1.78. MPEP 1481.03 contains criteria for granting a certificate of correction correcting benefit in an issued patent. See the section titled "Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits." In view of the foregoing, the petition shows compliance with the criteria for correction of benefit under Rule 1.78.

B. THE APPLICANT HAS COMPLIED WITH THE CRITERIA FOR CLAIMING BENEFIT TO 09/666,068

I. THE APPLICANT HAS COMPLIED WITH THE REQUIREMENTS OF 37 C.F.R. 1.78

The following paragraphs in this subsection identify requirements in Rule 1.78 for claiming priority, and show compliance with those requirements.

37 CFR 1.78(a)(1) authorizes a claim to priority to prior filed applications only if the applications name at least one common inventor and disclose the claimed invention. The prior filed application is 09/666,068. The common inventor is Edward L. Tobinick, M.D. Facts 14-39.

37 CFR 1.78(a)(1)(i) and (ii) require the prior filed applications to be either international applications or applications entitled to a filing date. The prior filed applications is 09/666,068, which was entitled to and accorded a filing date. Exhibit 1, Facts 14 - 15.

37 CFR 1.78(a)(2)(i) requires a claim to priority to be present or amended to be present during the pendency of the application, unless the application was filed prior to November 29, 2000, and to state the relationship between the applications. This application is an application filed under 111(a) after November 29, 2000. Accordingly, the amendment submitted herewith provides the specific references and relationships to 09/476,643, which is a continuation-in-part of 09/275,070, which is a continuation-in-part of 09/256,388.

37 CFR 1.78(a)(2)(iii) requires the claim to priority be presented in an application data sheet or amendment to the first sentence of the specification following the title. The amendment submitted herewith provides the claim to priority to 09/666,068 in the first sentence of the specification following the title.

37 CFR 1.78(a)(3) authorizes an amendment claiming priority after the time periods

specified by 1.78(a)(2)(ii) only if the late filing of the claim the priority was unintentionally delayed. The entire delay between the date the priority claim was due under paragraph 37 CFR 1.78 (a)(2)(ii) and the date of submission of the Petition was unintentional. Fact 40.

In view of the foregoing, this request should be granted.

Respectfully Submitted,

3-30-2010

/RobertHahl#33,893/

DATE

Robert W. Hahl, Ph.D.
Registration No. 33,893
Attorney of Record

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Approved for use through 6/30/99. OMB 0851-0033
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.502

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMINER	ART UNIT
	CLASS	SUBCLASS		
TOBINICK 3.0-009(CIP)(DIVII)			Examiner William R.A. Jarvis	1614

Address to:

**Assistant Commissioner for Patents
Washington, D.C. 20231**

This is a request for filing a continuation divisional application under 37 CFR 1.50, of pending prior Application Number 09/1476643, filed on 12/31/99, entitled INF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS.

1. Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 09/1476,643, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS	
	TOTAL CLAIMS (37 CFR 1.18(e))	17 - 20 =	--	x \$ _____ =	\$ --	
	INDEPENDENT CLAIMS (37 CFR 1.18(a))	1 - 3 =	--	x \$ _____ =	--	
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.18(d))			+ \$ _____ =		
				BASIC FEE (37 CFR 1.18(d))	+ \$345.00	
	Total of above Calculations =					
	Reduction by 60% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).					
	TOTAL =					\$345.00

Burden Hour Statement: This form is estimated to take 0.5 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Approved for use through 5/30/99. OMB 0651-0033
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

(REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, PAGE 2)

9. New formal drawings are enclosed.

10. Priority of foreign application number _____, filed on _____ in _____ is claimed under 35 U.S.C. 119(a) - (d).
 The certified copy has been filed in prior application number _____ / _____, filed _____.

11. A preliminary amendment is enclosed.

12. The prior application is assigned of record to _____

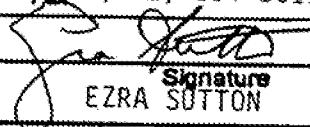
13. Also enclosed:

14. The power of attorney in the prior application is to: EZRA SUTTON, P.A.
Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095

a. The power of attorney appears in the original papers in the prior application.

b. Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)

<input type="checkbox"/> Customer Number	<input type="text"/>	→	<input type="text"/> Place Customer Number Bar Code Label here
OR			
Firm or <input checked="" type="checkbox"/> Individual Name	Type Customer Number here		
EZRA SUTTON, P.A.			
Address	Plaza 9, 900 Route 9		
Address			
City	Woodbridge	State	New Jersey ZIP 07095
Country			
Telephone	(732) 634-3520		
Fax	(732) 634-3511		
9-5-00			
Date	Signature		
EZRA SUTTON			

Inventor(s)
 Assignee of complete interest. Certification under 37 CFR 3.73(b) is enclosed.
 Attorney or agent of record
 Filed under 37 CFR 1.34(a) 25,770
 Registration number if acting under 37 CFR 1.34(a) _____

[Page 2 of 2] <

TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

RELATED APPLICATION

application is a divisional of 09/476,643, filed December 31, 1999, now U.S. Patent 6,177,077, which

This is a continuation-in-part of Application Serial No. 09/256,388, filed on

February 24, 1999.

2/27
4/15/01

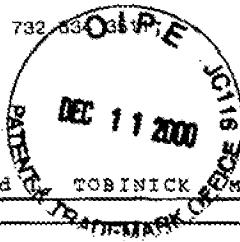
FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration

Exhibit 2_Pages41-45fromIFW_09666068_666.



J3

Applicant or Patentee: Edward L. TOBINICK, M.D.
 Serial or Patent No.: 09/666068
 Filed or Issued: 10/10/00
 Title: TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

Attorney's
Docket No.:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

described in:

the specification filed herewith
 Application Serial No. _____, filed _____
 Patent No. _____, issued _____

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

no such person, concern, or organization
 persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

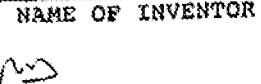
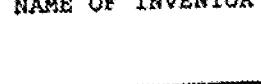
FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Edward L. TOBINICK, M.D.

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
		
Signature of Inventor	Signature of Inventor	Signature of Inventor

December 29, 1999

Date	Date	Date
------	------	------

DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK
3.0-009 (CIP)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL RETINAL AND MUSCULAR DISORDERS, the specification of which (check one) is attached hereto.

was filed on _____ as
Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520

Address all correspondence to _____

EZRA SUTTON, P.A.
Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Edward L. TOBINICK, M.D. Date December 29, 1999
Inventor's signature Edward L. TOBINICK, M.D. Date December 29, 1999
Residence Los Angeles, California 90024-6903 Citizenship United States of America
Post Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Full name of second joint inventor, if any _____
Second Inventor's signature _____ Date _____
Residence _____ Citizenship _____
Post Office Address _____

TOBINICK 3.0-009 (CIP) (DIV I)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BY FAX - 1-703-308-7751

TECH 3 2001
INTER 1600/2900In re patent application of:
EDWARD L. TOBINICK, M.D.

Serial No. 09/666,068 : Group Art Unit 1614

Filed: September 19, 2000 : Examiner

For: TNF INHIBITORS FOR THE
TREATMENT OF NEUROLOGICAL,
RETINAL AND MUSCULAR DISORDERS : December 6, 2000Assistant Commissioner for Patents
Washington, D.C. 20231CORRECTION OF FILING RECEIPT

Sir:

Please issue a corrected filing receipt, and correct the following data:

THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999,
WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED.

See the enclosed filing receipt.

Respectfully submitted,

EZRA SUTTON, P.A.

Ezra Sutton

EZRA SUTTON
Reg. No. 25,770

Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095
(732) 634-3520
BS/jmt

RECEIVED
OCT 12 2001
CIP/JCWS

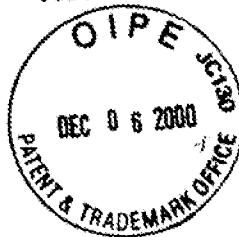
RECEIVED
OCT 12 2001
CIP/JCWS



UNITED STATES PATENT AND TRADEMARK OFFICE

SEARCHED | SERIALIZED | FILED REC'D | FATTY DOCKET NO. | DRAWINGS | TOT CLAIMS | IND CLAIMS |

09/19/2000 1614 345 TOBINICK 3,0-009 21 2



Ezra Sutton PA
Plaza 9 900 Route 9
Woodbridge, NJ 07095

Date Mailed: 11/15/2000

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Edward L. Tobinick, Los Angeles, CA ;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A CIP OF 09/256,388 02/24/1999 ABN

RECEIVED
DEC 13 2001
TECH CENTER 1600/2900

Foreign Applications

If Required, Foreign Filing License Granted 11/15/2000

**** SMALL ENTITY ****

Title

TNF inhibitors for the treatment of neurological, retinal and muscular disorders

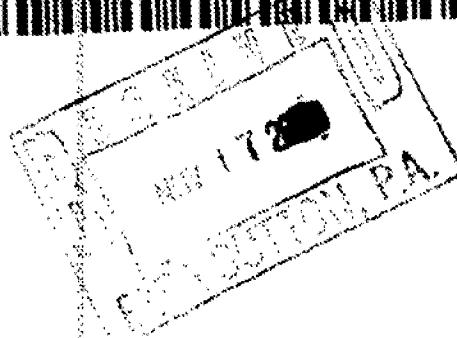
Preliminary Class

514

Data entry by : HINES, BRENDA

Team : OIPR

Date: 11/15/2000



FILE COPY

RECEIVED
FEB 13 2001
TECH CENTER 1600/2300

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Sib Data Sheet

SERIAL NUMBER 09/666,068	FILING DATE 12/11/2000 RULE	CLASS 514	GROUP ART UNIT 1614	ATTORNEY DOCKET NO. TOBINICK3.0-009 (CIP)(DIVI)
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APPLICANTS

Edward L. Tobinick, Los Angeles, CA ;

** CONTINUING DATA *****

THIS APPLICATION IS A DIV OF 09/476,643 12/31/1999 PAT 6,177,077
WHICH IS A CIP OF 09/256,388 02/24/1999 ABN

** FOREIGN APPLICATIONS *****

IF REQUIRED, FOREIGN FILING LICENSE
GRANTED ** 11/02/2000

** SMALL ENTITY **

Foreign Priority claimed	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Met after Allowance	CA	-	16	1
Verified and Acknowledged	Examiner's Signature Initials				

ADDRESS

EZRA SUTTON, P.A.
Plaza 9, 900 Route 9
Woodbridge, NJ 07095

TITLE

TNF inhibitors for the treatment of neurological, retinal and muscular disorders

FILING FEE RECEIVED 410	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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Exhibit 3_Pages 34-39fromIFW_09666068_666.pdf



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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 WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE RECD	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/666,068	12/11/2000	1614	410	TOBINICK3.0- 009(CIP)(DIV)I		16	1

CORRECTED FILING RECEIPT

EZRA SUTTON, P.A.
 Plaza 9, 900 Route 9
 Woodbridge, NJ 07095



"0C000000005761748"

Date Mailed: 01/24/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Edward L. Tobinick, Los Angeles, CA :

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A DIV OF 09/476,643 12/31/1999 PAT 6,177,077
 WHICH IS A CIP OF 09/256,388 02/24/1999 ABN

Foreign Applications

If Required, Foreign Filing License Granted 11/02/2000

**** SMALL ENTITY ******Title**

TNF inhibitors for the treatment of neurological, retinal and muscular disorders

Preliminary Class

514

Data entry by : BURSE, JANICE

Team : OIPE

Date: 01/24/2001





UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
 UNITED STATES PATENT AND TRADEMARK OFFICE
 WASHINGTON, D.C. 20591
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/666,068	12/11/2000	1614	410	TOBINICK3.0-009(CIP)(DIV)		16	1

CONFIRMATION NO. 6420
FILING RECEIPT

EZRA SUTTON, P.A.
 Plaza 9, 900 Route 9
 Woodbridge, NJ 07095



"OC000000005791231"

Date Mailed: 02/22/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Edward L. Tobinick, Los Angeles, CA;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A DIV OF 09/476,643 12/31/1999 PAT 6,177,077
 WHICH IS A CIP OF 09/256,388 02/24/1999 ABN

Foreign Applications

If Required, Foreign Filing License Granted 11/02/2000

Projected Publication Date: 05/31/2001

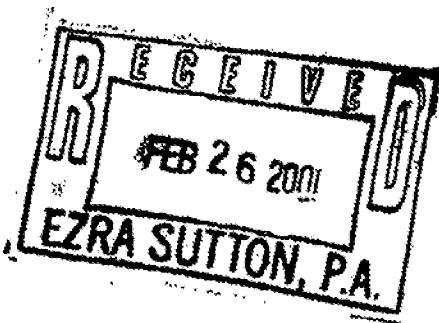
Non-Publication Request: No

Early Publication Request: No

" SMALL ENTITY "

Title

TNF inhibitors for the treatment of neurological, retinal and muscular disorders



TOBINICK 3.0-009 (CIP) (DIV II)



Sector
3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
EDWARD L. TOBINICK, M.D.

Serial No. 09/666,068 : Group Art Unit 1614

Filed: September 19, 2000 : Examiner

For: TNF INHIBITORS FOR THE
TREATMENT OF NEUROLOGICAL,
RETINAL AND MUSCULAR DISORDERS

Assistant Commissioner for Patents
Washington, D.C. 20231

Attention: Customer Service Center
Initial Patent Examination Division

RESPONSE

Sir:

This is in response to the "Notice to File Missing Parts of Nonprovisional Application," dated November 2, 2000.

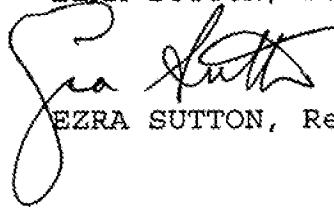
Enclosed for filing are the following:

1. Page 54, which was missing from the application;
2. A copy of the Declaration from the parent application (U.S. Serial No. 09/476,643);
3. A copy of the Verified Statement for a Small Entity from the parent application (U.S. Serial No. 09/476,643);
4. The surcharge fee of \$65 for a small entity; and
5. A copy of the Notice to File Missing Parts of Nonprovisional Application.

It is requested that this application be given a new filing date upon receipt of this Response.

Respectfully submitted,

EZRA SUTTON, P.A.



EZRA SUTTON, Reg. No. 25,770

Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095

(732) 634-3520

ES/jmt

Enclosures

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO:
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231 ON

Date December 6, 2000
By Judith M. Traine

US 6,379,666 B1

1

TNF INHIBITORS FOR THE TREATMENT
OF NEUROLOGICAL, RETINAL AND
MUSCULAR DISORDERS

RELATED APPLICATION

This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned.

FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration of unknown etiology. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmacologic agents, which are often not completely successful.

These neurological conditions include acute spinal cord traumas, spinal cord compression, spinal cord hematomas, cord concussion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic nerve compression, neuropathy, and pain; but also including cervical disc herniation, causing nerve compression in the neck; acute or chronic spinal cord compression from cancer (this is usually due to metastases to the spine, such as from prostate, breast or lung cancer); autoimmune disease of the nervous system; and demyelinating diseases, the most common condition being multiple sclerosis.

Steroid drugs such as cortisone that are used to treat many of the aforementioned neurological problems and conditions are particularly hazardous because they are used either at high dosage, with a corresponding increasing risk of side effects, or because they are used chronically, also increasing their adverse effects. Lastly, steroids are only partially effective or completely ineffective.

Tumor necrosis factor (TNF), a naturally occurring cytokine, plays a central role in the inflammatory response and in immune injury. TNF is formed by the cleavage of a precursor transmembrane protein, forming soluble molecules which aggregate to form trimolecular complexes. These complexes then bind to receptors found on a variety

2

of cells. Binding produces an array of pro-inflammatory effects, including release of other pro-inflammatory cytokines, including interleukin (IL)-6, IL-8, and IL-1; release of matrix metalloproteinases; and up regulation of the expression of endothelial adhesion molecules, further amplifying the inflammatory and immune cascade by attracting leukocytes into extravascular tissues. TNF is now well established as key in the pathogenesis of rheumatoid arthritis (RA) and Crohn's Disease.

Specific inhibitors of TNF, only recently commercially available, now provide the possibility of therapeutic intervention in TNF mediated diseases. Dramatic therapeutic success has already been demonstrated with infliximab, a chimeric anti-TNF monoclonal antibody (mAb), in treating Crohn's Disease and RA; and with etanercept, a recombinant fusion protein consisting of two soluble TNF receptors joined by the Fc fragment of a human IgG1 molecule, in treating RA and Psoriatic Arthritis. Other specific anti-TNF agents are under development, including D2E7 (a human anti-TNF mAb), CDP 571 (a chimeric, but 95% humanized, anti-TNF mAb), and a pegylated soluble TNF type 1 receptor. Additionally, thalidomide has been demonstrated to be a potent anti-TNF agent. Further, anti-TNF therapies may include gene therapy and the development of selective inhibitors of the TNF-alpha converting enzyme.

As with other organ systems, TNF has been shown to have a key role in the central nervous system. There is a need for TNF inhibitors that will open a new realm of therapeutic possibilities for a wide variety of neurological and related disorders. These disorders are diverse and include inflammatory and autoimmune disorders of the nervous system, including multiple sclerosis, Guillain Barre syndrome, and myasthenia gravis; degenerative disorders of the nervous system, including Alzheimer's disease, Parkinson's disease and Huntington's disease; disorders of related systems of the retina and of muscle, including optic neuritis, macular degeneration, diabetic retinopathy, dermatomyositis, amyotrophic lateral sclerosis, and muscular dystrophy; and injuries to the nervous system, including traumatic brain injury, acute spinal cord injury, and stroke.

The limited ability of the body to effect repair after injury to the nervous system, the devastating nature of these diseases and the lack of effective therapy all highlight the importance of early therapy aimed at preventing or limiting neuronal destruction. Anti-TNF therapies are ideally suited to this task because they have been demonstrated to dramatically limit inflammation by interrupting the inflammatory cascade at a fundamental level.

There remains a need for a new pharmacologic treatment of these aforementioned physiological problems of the nervous system associated with autoimmune disease, demyelinating diseases, neurodegenerative diseases, trauma, injuries and compression with the pharmacological use of TNF antagonists or TNF blockers, which are greatly beneficial for the large number of patients whom these conditions affect. Drugs which are powerful TNF blockers are etanercept, infliximab, pegylated soluble TNF Receptor Type I (PEGS TNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibodies), thalidomide, phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV inhibitors. Etanercept or infliximab may be used for the immediate, short term and long term (acute and chronic) blockade of TNF in order to minimize neurological damage mediated by TNF dependent processes occurring in the aforementioned neurological disorders. The use of these TNF antagonists or TNF blockers would result in the amelioration of these physiological neurological problems.

DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK

3.0-009 (CIP)

As a below named inventor, I hereby declare that: Exhibit S_Pages170-172fromIFW_09476643_077.pdf

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, the specification of which

RETINAL AND MUSCULAR DISORDERS(check one) is attached hereto. was filed on _____ as

Application Serial No. _____

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520
Address all correspondence to _____

EZRA SUTTON, P.A.

Plaza 9, 900 Route 9

Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Edward L. TOBINICK, M.D.

Inventor's signature Edward L. TOBINICK, M.D. Date December 29, 1999

Residence Los Angeles, California 90024-6903 Citizenship United States of America

Post Office Address 100 UCLA Medical Plaza, Suite 205

Los Angeles, California 90024-6903

Full name of second joint inventor, if any _____

Second Inventor's signature _____ Date _____

Residence _____ Citizenship _____

Post Office Address _____

Applicant or Patentee: Edward L. TOBINICK, M.D.Attorney's
Docket No.:

Serial or Patent No.:

Filed or Issued:

Title: TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,
RETINAL AND MUSCULAR DISORDERS**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR**

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark office with regard to the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

described in:

the specification filed herewith
 Application Serial No. _____, filed _____
 Patent No. _____, issued _____

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

no such person, concern, or organization
 persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____

ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

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Edward L. TOBINICK, M.D.

NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR


Signature of Inventor Signature of Inventor Signature of Inventor

December 29, 1999

Date Date Date

SERIAL NUMBER 09/476,643	FILED DATE 12/31/99	CLASS 514	GROUP ART UNIT 1614	ATTORNEY DOCKET NO. TOBINICK.3.0
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APPLICANT

EDWARD L. TOBINICK, LOS ANGELES, CA.

CONTINUING DOMESTIC DATA***

VERIFIED THIS APPLN IS A CIP OF 09/275,070 03/23/99 PAT 6,015,557
ASJ WHICH IS A CIP OF 09/256,388 02/24/99 ABN

371 (NAT'L STAGE) DATA***

VERIFIED

ASJ

NONE

FOREIGN APPLICATIONS***

VERIFIED

ASJ

NONE

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 02/07/00 ** SMALL ENTITY **

Foreign Priority claimed 35 USC 119 (a-d) conditions met	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY CA	SHEETS DRAWING 0	TOTAL CLAIMS 99	INDEPENDENT CLAIMS 8
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Verified and Acknowledged <i>ASJ</i>	Examiner's Initials <i>ASJ</i>
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ADDRESS EZRA SUTTON PA PLAZA 9 900 ROUTE 9 WOODBRIDGE NJ 07095

TITLE TNT INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL RETINAL AND MUSCULAR DISORDERS
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8/24/00*

FILING FEE RECEIVED \$501	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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12/31/99
JCS 09/09/99 PTO

01-65-00

Exhibit 6_Pages112-114fromIFW_09476643_077.pdf

JCS 09/09/99 PTO
09/476643
12/31/99
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A PROFESSIONAL CORPORATION

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900 ROUTE 9

WOODBRIDGE, NEW JERSEY 07095

EZRA SUTTON*

OF COUNSEL

ROBERT A. GREEN

DAVID L. DAVIS

PATENTS

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FAX: (732) 634-3511

BY EXPRESS MAIL

*MEMBER OF N.J. AND N.Y. BARS

Assistant Commissioner for Patents
Washington, D.C. 20231

File No.: TOBINICK 3.0-009 (CIP)

Inventor(s): Edward L. TOBINICK

Title: TNFIIINHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,
RETINAL AND MUSCULAR DISORDERS

Assignee: None

Dear Sir:

Enclosed herewith are the following documents in the above-
identified application for a Letters Patent of the United States:

2 Pages of Abstract Verified Statement for Small Entity Status
 29 Pages of Specification Declaration, Power of Attorney & Petition
 99 Number of Claims Two (2) return-addressed postcards
 4 Sheets of Drawings (PLEASE PROVIDE FILING DATE & SERIAL NUMBER)
 Assignment for Recording (attached to copy of this letter)
 PETITION TO MAKE SPECIAL; LIST OF PRIOR ART CITED BY APPLICANT; 3 PRIOR
5 PRIOR ART PATENTS; FEE OF \$130
Check No. 3884 in the amount of \$510 calculated as follows:

Basic Fee (**Large Business \$760.00) (*Small Business \$380.00) \$ 380

Additional Fees:

Total number of claims 99

Total number of claims in excess of 20, 79 times (**\$18)(*\$9) 711

Number of independent claims 8

Number of independent claims minus 3, 5 times (**\$78)(*\$39) 195

Assignment recording fee (\$40)

Multiple dependent claims (**\$260) (*\$130)

PETITION TO MAKE SPECIAL

\$1,286

130

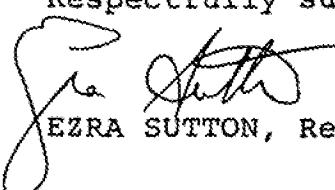
\$1,416

TOTAL filing and assignment recording fees

CONVENTION DATE _____ for _____ Appln. No. _____
is claimed.

Priority Document: _____ Enclosed _____ Will follow

Respectfully submitted,



EZRA SUTTON, Reg No. 25,770

ES/jmt
Enclosures

5 **TNF INHIBITORS FOR THE TREATMENT OF
NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS**

RELATED APPLICATION

WAC
This is a continuation-in-part of Application Serial No. 09/256,388, filed on
February 24, 1999.

FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

15
20

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration



Bib Data Sheet



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

FILE COPY

SERIAL NUMBER 09/476,643	FILING DATE 12/31/1999 RULE -	CLASS 514	GROUP ART UNIT 1614	ATTORNEY DOCKET NO. TOBINICK.3.0
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APPLICANTS

EDWARD L. TOBINICK, LOS ANGELES, CA

This Appln is a CTRIED PAT# 9/275,070 6015,557

** CONTINUING DATA ***** WHICH THIS APPLICATION IS A CIP OF 09/256,388 02/24/1999 ABN

** FOREIGN APPLICATIONS *****

IF REQUIRED, FOREIGN FILING LICENCE GRANTED SMALL ENTITY **
** 02/07/2000

RECEIVED MAR 27 2000

TECH CENTER 1600/2800

Foreign Priority claimed	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	STATE OR COUNTRY CA	SHEETS DRAWING	TOTAL CLAIMS 99	INDEPENDENT CLAIMS 8
35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Met after Allowance				
Verified and Acknowledged	Examiner's Signature EPA	Initials			

ADDRESS

EZRA SUTTON PA
PLAZA 9 900 ROUTE 9
WOODBRIDGE, NJ 07095

TITLE

TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

FILING FEE RECEIVED 510	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other <input type="checkbox"/> Credit
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01-05-00

JCS3 U.S. PRO
09/476643

12/31/99
A

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EZRA SUTTON, P. A.

A PROFESSIONAL CORPORATION

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WOODBRIDGE, NEW JERSEY 07095

EZRA SUTTON*

OF COUNSEL

ROBERT A. GREEN

DAVID L. DAVIS

December 31, 1999

*MEMBER OF N.J. AND N.Y. BAR

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FAX: (732) 634-3511

Assistant Commissioner for Patents
Washington, D.C. 20231

File No.: TOBINICK 3.0-009 (CIP)

Inventor(s): Edward L. TOBINICK

Title: TNF1INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,
RETINAL AND MUSCULAR DISORDERS

Assignee: None

Dear Sir:

Enclosed herewith are the following documents in the above-
identified application for a Letters Patent of the United States:

2 Pages of Abstract Verified Statement for Small Entity Status
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 9 Number of Claims Two (2) return-addressed postcards
 - Sheets of Drawings (PLEASE PROVIDE FILING DATE & SERIAL NUMBER)
 - Assignment for Recording (attached to copy of this letter)
 PETITION TO MAKE SPECIAL; LIST OF PRIOR ART CITED BY APPLICANT; .. .
5 PRIOR ART PATENTS; FEE OF \$130

Check No. 3884 in the amount of \$510 _(\$380 + \$130), calculated as follows:

Basic Fee (**Large Business \$760.00) (*Small Business \$380.00) \$ 380
Additional Fees:

Total number of claims 99

Total number of claims in excess of 20, 79 times (**\$18)(*\$9) 711

Number of independent claims 8

Number of independent claims minus 3, 5 times (**\$78)(*\$39) 195

Assignment recording fee (\$40)

Multiple dependent claims (**\$260) (*\$130)

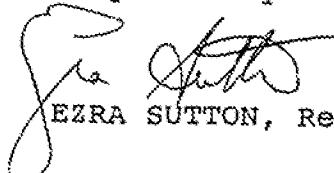
PETITION TO MAKE SPECIAL 130

TOTAL filing and assignment recording fees \$1,416

CONVENTION DATE _____ for _____ Appln. No. _____
is claimed.

Priority Document: Enclosed Will follow

Respectfully submitted,



EZRA SUTTON, Reg No. 25,770

ES/jmt
Enclosures

Applicant or Patentee: Edward L. TOBINICK, M.D. Attorney's
 Serial or Patent No.: _____ Docket No.: _____
 Filed or Issued: _____
 Title: TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,
 RETINAL AND MUSCULAR DISORDERS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
 STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR**

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark office with regard to the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

described in:
 the specification filed herewith
 Application Serial No. _____, filed _____
 Patent No. _____, issued _____

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

no such person, concern, or organization
 persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
 INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1601 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Edward L. TOBINICK, M.D.

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
	Signature of Inventor	Signature of Inventor
Signature of Inventor	Signature of Inventor	Signature of Inventor

December 29, 1999

Date	Date	Date
------	------	------

**TNF INHIBITORS FOR THE TREATMENT OF
NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS**

RELATED APPLICATION

This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999.

FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration

Exhibit 8_Pages23-24fromIFW_09476643_077.pdf

1490

MANUAL OF PATENT EXAMINING PROCEDURE

PTO/SB/23 (10-98)

Approved for use through 10/01/00. GMB 02/01/00

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBLIGATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

Docket Number (Optional)
TOBINICK 3 00-009
(CIP)

In re Application of: **EDWARD L. TOBINICK**
 Application No. **09/476,643**
 Filed: **December 31, 1999**
 For: **TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL RETINAL AND MUSCULAR DISORDERS**

The owner, **EDWARD L. TOBINICK**, 0.00 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 6,015,557. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer. In the event that it later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. The undersigned is an attorney of record.

 July 20, 2000
Signature Date

EZRA SUTTON

Typed or printed name

Terminal disclaimer fee under 37 CFR 1.20(d) included.

*Certification under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/26 may be used for making this certification. See MPEP § 324.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

DECLARATION FOR PATENT APPLICATION

OFFICIAL

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS**, the specification of which

(check one) is attached hereto.

was filed on _____ as
Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

09/256,388	February 24, 1999	Abandoned
(Application Serial No.) 09/275,070	(Filing Date) March 23, 1999	(Status—patented, pending, abandoned) U.S. Patent No. 6,015,557
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520
Address all correspondence to _____
EZRA SUTTON, P.A.
Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Edward A. Tobinick, M.D.

Inventor's signature Edward A. Tobinick Date July 19, 2000

Residence Los Angeles, California Citizenship United States of America

Post Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Full name of second joint inventor, if any _____

Second Inventor's signature _____ Date _____

Residence _____ Citizenship _____

Post Office Address _____

(Supply similar information and signature for third and subsequent joint inventors)

Exhibit 9_Pages18-18fromIFW_09476643_077.pdf

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EZRA SUTTON, P. A. FAX RECEIVED

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WOODBRIDGE, NEW JERSEY 07095

JUL 24 2000

GROUP 1600

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COPYRIGHTS(732) 634-3520
FAX: (732) 634-3511EZRA SUTTON
JOSEPH SUTTON
OF COUNSEL
ROBERT A. GREEN
DAVID L. DAVIS

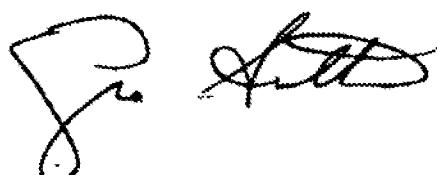
*MEMBER OF N.J. AND N.Y. BARS

Date 7/20/00TO: EXR JARVISFAX NO. 703-308-4556FROM: EZRA SUTTONFAX NO. 1-732-634-3511PHONE: 1-732-634-3520

OFFICIAL

TOTAL NUMBER
OF PAGES: 8

Amendment Enclosed.



TOBINICK 3.0-009 (CIP)

OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BY FAX AND MAIL

In re patent application of:
EDWARD L. TOBINICK

Serial No.: 09/476,643

Group Art Unit 1614

Filed: December 31, 1999

Examiner William R. A. Jarvis

For: TNF INHIBITORS FOR THE
TREATMENT OF NEUROLOGICAL,
RETINAL, AND MUSCULAR
DISORDERS

July 20, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231AMENDMENT

Sir:

This is in response to the first Office Action.

IN THE SPECIFICATION:

Please amend the first sentence of the specification as follows:

Al

application 09/275,070
-- This is a continuation-in-part of Application Serial No. 09/256,388, filed on
March 23, 1999 U.S. Patent 6,015,557, which is a continuation-in-part of
February 24, 1999, now abandoned, and Application Serial No. 09/275,070, now U.S. Patent
09/256,388, filed February 24, 1999,
now abandoned
No. 6,015,557. --

8/24/00

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE UNITED STATES POSTAL
SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO:
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WASHINGTON, D.C. 20231 ON

DATE

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US 6,177,077 B1

1

TNT INHIBITORS FOR THE TREATMENT
OF NEUROLOGICAL DISORDERS

RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 09/275,070, filed on Mar. 23, 1999, now U.S. Pat. No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed Feb. 24, 1999 now abandoned.

FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration of unknown etiology. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmacologic agents, which are often not completely successful.

These neurological conditions include acute spinal cord trauma, spinal cord compression, spinal cord hematoma, cord contusion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic nerve compression, neuropathy, and pain; but also including cervical disc herniation, causing nerve compression in the neck; acute or chronic spinal cord compression from cancer (this is usually due to metastases to the spine, such as from prostate, breast or lung cancer); autoimmune disease of the nervous system; and demyelinating diseases, the most common condition being multiple sclerosis.

Steroid drugs such as cortisone that are used to treat many of the aforementioned neurological problems and conditions are particularly hazardous because they are used either at high dosage, with a corresponding increasing risk of side effects, or because they are used chronically, also increasing their adverse effects. Lastly, steroids are only partially effective or completely ineffective.

Tumor necrosis factor (TNF), a naturally occurring cytokine, plays a central role in the inflammatory response and in immune injury. TNF is formed by the cleavage of a precursor transmembrane protein, forming soluble molecules which aggregate to form trimolecular complexes. These complexes then bind to receptors found on a variety of cells. Binding produces an array of pro-inflammatory

2

effects, including release of other pro-inflammatory cytokines, including interleukin (IL)-6, IL-8, and IL-1; release of matrix metalloproteinases; and up regulation of the expression of endothelial adhesion molecules, further amplifying the inflammatory and immune cascade by attracting leukocytes into extravascular tissues. TNF is now well established as key in the pathogenesis of rheumatoid arthritis (RA) and Crohn's Disease.

Specific inhibitors of TNF, only recently commercially available, now provide the possibility of therapeutic intervention in TNF mediated diseases. Dramatic therapeutic success has already been demonstrated with infliximab, a chimeric anti-TNF monoclonal antibody (mAb), in treating Crohn's Disease and RA; and with etanercept, a recombinant fusion protein consisting of two soluble TNF receptors joined by the Fc fragment of a human IgG1 molecule, in treating RA and Psoriatic Arthritis. Other specific anti-TNF agents are under development, including D2E7 (a human anti-TNF mAb), CDP 571 (a chimeric, but 95% humanized, anti-TNF mAb), and a pegylated soluble TNF type 1 receptor. Additionally, thalidomide has been demonstrated to be a potent anti-TNF agent. Further, anti-TNF therapies may include gene therapy and the development of selective inhibitors of the TNF-alpha converting enzyme.

As with other organ systems, TNF has been shown to have a key role in the central nervous system. There is a need for TNF inhibitors that will open a new realm of therapeutic possibilities for a wide variety of neurological and related disorders. These disorders are diverse and include inflammatory and autoimmune disorders of the nervous system, including multiple sclerosis, Guillain Barre syndrome, and myasthenia gravis; degenerative disorders of the nervous system, including Alzheimer's disease, Parkinson's disease and Huntington's disease; disorders of related systems of the retina and of muscle, including optic neuritis, macular degeneration, diabetic retinopathy, dermatomyositis, amyotrophic lateral sclerosis, and muscular dystrophy; and injuries to the nervous system, including traumatic brain injury, acute spinal cord injury, and stroke.

The limited ability of the body to effect repair after injury to the nervous system, the devastating nature of these diseases and the lack of effective therapy all highlight the importance of early therapy aimed at preventing or limiting neuronal destruction. Anti-TNF therapies are ideally suited to this task because they have been demonstrated to dramatically limit inflammation by interrupting the inflammatory cascade at a fundamental level.

There remains a need for a new pharmacologic treatment of these aforementioned physiological problems of the nervous system associated with autoimmune disease, demyelinating diseases, neurodegenerative diseases, trauma, injuries and compression with the pharmacological use of TNF antagonists or TNF blockers, which are greatly beneficial for the large number of patients whom these conditions affect. Drugs which are powerful TNF blockers are etanercept, infliximab, pegylated soluble TNF Receptor Type 1 (PEGs TNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibodies), thalidomide, phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV inhibitors. Etanercept or infliximab may be used for the immediate, short term and long term (acute and chronic) blockade of TNF in order to minimize neurological damage mediated by TNF dependent processes occurring in the aforementioned neurological disorders. The use of these TNF antagonists or TNF blockers would result in the amelioration of these physiological neurological problems.

jc549 U.S. PRO
03/23/99

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A PROFESSIONAL CORPORATION

PLAZA 9

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EZRA SUTTON*
OF COUNSEL
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BY EXPRESS MAIL

*MEMBER OF NJ AND NY BARS

Assistant Commissioner for Patents
Washington, D.C. 20231

jc549 U.S. PRO
09/275070
03/23/99

File No.: TOBINICK 3.0-007 (CIP)
Inventor(s): Dr. Edward L. Tobinick
Title: TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE
TREATMENT OF NEUROLOGICAL DISORDERS

Assignee: None

Dear Sir:

Enclosed herewith are the following documents in the above-identified application for a Letters Patent of the United States:

1	Pages of Abstract	<input checked="" type="checkbox"/> Verified Statement for Small Entity Status
21	Pages of Specification	Declaration, Power of Attorney & Petition
47	Number of Claims	Two (2) return-addressed postcards
none	Sheets of Drawings	(PLEASE PROVIDE FILING DATE & SERIAL NUMBER)
none	Assignment for Recording (attached to copy of this letter)	
<input checked="" type="checkbox"/>	PETITION TO MAKE SPECIAL; LIST OF PRIOR ART CITED BY APPLICANT; 3 PRIOR ART PATENTS; FEE (\$130)	

Check No. 3002 in the amount of \$753.00, calculated as follows:

Basic Fee (**Large Business \$760.00) (*Small Business \$380.00)	\$380.00
Additional Fees:	
Total number of claims 47	
Total number of claims in excess of 20, 27 times (**\$18) (*\$9)	243.00
Number of independent claims 2	
Number of independent claims minus 3, --times (**\$78) (*\$39)	---
Assignment recording fee (\$40)	---
Multiple dependent claims (**\$260) (*\$130)	---

TOTAL filing and assignment recording fees \$623.00

PETITION TO MAKE SPECIAL FEE 130.00

CONVENTION DATE _____ for _____ Appln. No. _____ \$753.00
is claimed.

Priority Document: _____ Enclosed _____ Will follow

Respectfully submitted,

EZRA SUTTON, Reg. No. 25,770

ES/jmt
Enclosures

TUMOR NECROSIS FACTOR ANTAGONISTS FOR
THE TREATMENT OF NEUROLOGICAL DISORDERS

RELATED APPLICATION

5 This is a continuation-in-part of Application Serial No. 09/956,388, filed on February 24, 1999.

FIELD OF THE INVENTION

10 The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; or demyelinating 15 neurological disorders, including multiple sclerosis. More particularly, the TNF antagonists or TNF blockers, with or without the concurrent administration of methotrexate or Leflunomide, are used in a new treatment of these disorders by inhibiting the action 20 of TNF in the cells of the human body. The use of these TNF antagonists or TNF blockers with methotrexate or Leflunomide results in the amelioration of these neurological conditions.

BACKGROUND OF THE INVENTION

25 Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery

DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK
3.0-007 (CIP)

As a below named inventor, I hereby _____ that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT _____, the specification of which
OF NEUROLOGICAL DISORDERS

(check one) is attached hereto.

was filed on _____ as
 Application Serial No. _____
 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

09/256,388 (Application Serial No.)	24 February 1999 (Filing Date)	pending (Status—patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520
 Address all correspondence to _____
 EZRA SUTTON, P.A.
 Plaza 9, 900 Route 9
 Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Dr. Edward L. TOBINICK
 Inventor's signature X Date 3-20-99
 Residence Los Angeles, California 90024-6903 Citizenship United States of America

Post Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Full name of second joint inventor, if any Arthur Jerome TOBINICK
 Second Inventor's signature X Date 3-20-99
 Residence Los Angeles, California 90024-6903 Citizenship United States of America
 Post Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Dr. Edward L. TOBINICK
Arthur J. TOBINICK
Applicant or Patentee:
Serial or Patent No.:
Filed or Issued: _____

Attorney's
Docket No.: TOBINICK

Title: TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE
TREATMENT OF NEUROLOGICAL DISORDERS

3.0-007 (cip)

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

described in:

the specification filed herewith
 Application Serial No. _____, filed _____
 Patent No. _____, issued _____

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

no such person, concern, or organization
 persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

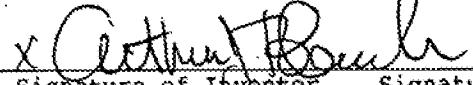
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dr. Edward L. TOBINICK
NAME OF INVENTOR

Arthur Jerome TOBINICK
NAME OF INVENTOR

NAME OF INVENTOR


Signature of Inventor


Signature of Inventor


Signature of Inventor

3-20-99

3-20-99

Date

Date

Date

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of :
DR. EDWARD L. TOBINICK, et al :

Serial No. : Group Art Unit

Filed: : Examiner

For: TUMOR NECROSIS FACTOR : March 23, 1999
ANTAGONISTS FOR THE :
TREATMENT OF NEUROLOGICAL :
DISORDERS :

JC545 U S P T O
09/275070
03/23/99

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION TO MAKE SPECIAL
(MPEP Section 708.02)

Sir:

Applicant hereby files this Petition to make special this application for purposes of examination and payment of the issue fee, on the grounds of a pre-examination search. Applicant also submits the petition fee.

The application presents claims directed to a single invention. In case the Examiner believes that there is more than one invention, applicant hereby elects without traverse Claims 27 to 47.

SEARCH AREAS

A pre-examination search was made of the records of the U.S. Patent Office by applicant's attorney, Ezra Sutton. The field of search included Class 424, Subclasses 85.1, 133.1, 134.1, 143.1,

144.1, 145.1, and 158.1; Class 435, Subclasses 69.1, 69.7, 172.3, and 240.27; and Class 530, Subclasses 350, 351, 387.1, 387.3, 388.2, 388.23, 388.4, 866, and 868. Also, a computer search was performed using the terms TNF and tumor necrosis factor.

INVENTION SEARCHED

A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing damage to neuronal tissue or for modulating the immune response affecting neuronal tissue of the human. The TNF antagonist administered is selected from the group consisting of etanercept and infliximab. The TNF antagonist is administered subcutaneously, intravenously, intrathecally, or intramuscularly.

Methotrexate or Leflunomide may be administered concurrently with the TNF antagonist for demyelinating diseases and certain other neurological disorders.

PATENTS SELECTED IN SEARCH

U.S. Patent Nos.: 5,605,690
5,656,272
5,795,967

A copy of each patent is enclosed.

DISCUSSION OF PATENTS

U.S. Patent No. 5,605,690 discloses using TNF antagonists to suppress TNF-dependent inflammatory diseases, such as arthritis. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

U.S. Patent No. 5,656,272 discloses using TNF antagonists to treat Crohn's disease. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

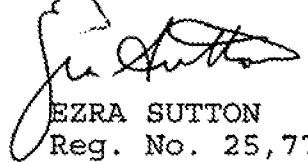
U.S. Patent No. 5,795,967 discloses using TNF antagonists to treat certain autoimmune diseases, such as arthritis, systemic lupus, and Crohn's disease. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

CONCLUSION

None of the prior art patents disclose or teach the specific subject matter recited in independent Claims 1 or 27, or render them obvious. Accordingly, this Petition should be granted.

Respectfully submitted,

EZRA SUTTON, P.A.



EZRA SUTTON
Reg. No. 25,770

Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095
(732) 634-3520

ES/jmt

Enclosures

SERIAL NUMBER	FILED DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO
09/275,070	03/23/1999	424	1614	TOBINICK-3.0

APPLICANT

EDWARD L TOBINICK, LOS ANGELES, CALIFORNIA; ARTHUR JEROME TOBINICK, LOS ANGELES, CALIFORNIA.

CONTINUING DOMESTIC DATA***

VERIFIED THIS APPLN IS A CIP OF 09/256,388 02/24/1999

371 (NAT'L STAGE) DATA***

VERIFIED

FOREIGN APPLICATIONS***

VERIFIED

FOREIGN FILING LICENSE GRANTED 05/07/1999

SMALL ENTITY

Foreign priority claimed 35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
Verified and acknowledged	Examiner's Name Initials	CA	0	47	2

ADDRESS

EZRA SUTTON P A
PLAZA 9
900 ROUTE 9
WOODBRIDGE , NJ 07095

TITLE

TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

FILING FEE RECEIVED \$**623	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of Time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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6,015,557

1

**TUMOR NECROSIS FACTOR ANTAGONISTS
FOR THE TREATMENT OF
NEUROLOGICAL DISORDERS**

RELATED APPLICATION

This is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned.

FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; or demyelinating neurological disorders, including multiple sclerosis. More particularly, the TNF antagonists or TNF blockers, with or without the concurrent administration of methotrexate or Leflunomide, are used in a new treatment of these disorders by inhibiting the action of TNF in the cells of the human body. The use of these TNF antagonists or TNF blockers with methotrexate or Leflunomide results in the amelioration of these neurological conditions.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmacologic agents, which are often not completely successful.

These neurological conditions include acute spinal cord trauma, spinal cord compression, spinal cord hematoma, cord contusion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic nerve compression, neuropathy, and pain; but also including cervical disc herniation, causing nerve compression in the neck; carpal tunnel syndrome (non-RA); acute or chronic spinal cord compression from cancer (this is usually due to metastases to the spine, such as from prostate, breast or lung cancer); autoimmune disease of the nervous system; and demyelinating diseases, the most common condition being multiple sclerosis.

Steroid drugs, such as cortisone that are used to treat the aforementioned neurological problems and conditions are particularly hazardous because they are used either at high dosage, with corresponding increasing risk of side effects, or because they are used chronically, also increasing their adverse effects. Lastly, steroids are only partially effective or completely ineffective.

There remains a need for a new pharmacologic treatment of these aforementioned physiological problems of the nervous system associated with autoimmune disease, demyelinating diseases, trauma, injuries and compression; with the pharmacological use of TNF antagonists or TNF blockers, which are greatly beneficial for the large number of patients whom these conditions affect. Two new drugs which are powerful TNF blockers are etanercept and infliximab. Etanercept or infliximab may be used for the immediate, short term and long term (acute and chronic) blockade of TNF in order to minimize neurologic damage mediated by TNF dependent processes occurring in the aforementioned neu-

2

rological disorders. The use of these TNF antagonists or TNF blockers would result in the amelioration of these physiological neurological problems. Concurrent administration of methotrexate or Leflunomide with either etanercept or infliximab is the preferred treatment for demyelinating diseases and certain other neurological disorders.

DESCRIPTION OF THE PRIOR ART

Pharmacologic chemical substances, compounds and agents which are used for the treatment of neurological disorders, trauma, injuries and compression having various organic structures and metabolic functions have been disclosed in the prior art. For example, U.S. Pat. Nos. 5,756,482 and 5,574,022 to ROBERTS et al disclose methods of attenuating physical damage to the nervous system and to the spinal cord after injury using steroid hormones or steroid precursors such as pregnenolone, and pregnenolone sulfate in conjunction with a non-steroidal anti-inflammatory substance such as indomethacin. These prior art patents do not teach the use of a TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat neurological disease, trauma, injury or compression, or autoimmune neurologic disease as in the present invention.

U.S. Pat. No. 5,605,690 to JACOBS discloses a method for treating TNF-dependent inflammatory diseases such as arthritis by administering a TNF antagonist, such as soluble human TNFR (a sequence of amino acids), to a human. This prior art patent does not teach the use of a TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat neurological disease, trauma, injury or compression, or demyelinating neurologic disease, as in the present invention.

U.S. Pat. No. 5,656,272 to LE et al discloses methods of treating TNF-alpha-mediated Crohn's disease using chimeric anti-TNF antibodies. This prior art patent does not teach the use of a TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat neurological trauma, injury or compression, or autoimmune neurologic disease, as in the present invention.

U.S. Pat. No. 5,650,396 discloses a method of treating multiple sclerosis (MS) by blocking and inhibiting the action of TNF in a patient. This prior art patent does not teach the use of the TNF antagonist as in the present invention.

None of the prior art patents disclose or teach the use of the TNF antagonist or TNF blocker of the present invention with the concurrent administration of methotrexate or Leflunomide for suppression and inhibition of the action of TNF in a human to treat neurological disease, trauma, injury or compression, or demyelinating neurologic disease, in which the TNF antagonist gives the patient a better opportunity to heal, slows disease progression, prevents neurological damage, or otherwise improves the patient's health.

Accordingly, it is an object of the present invention to provide a TNF antagonist, with or without the concurrent administration of methotrexate or Leflunomide, for a new pharmacologic treatment of neurological disorders, trauma, injuries and compression affecting the nervous system of the human body, or demyelinating neurologic disease, such that the use of these TNF antagonists will result in the amelioration of these neurological conditions.

Another object of the present invention is to provide a TNF antagonist, with or without the concurrent administration of methotrexate or Leflunomide, for providing suppression and inhibition of the action of TNF in a human to treat neurological injury, trauma or compression, or demyelinating neurologic disease.

DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK
3.0-007

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT, the specification of which

OF NEUROLOGICAL DISORDERS(check one) is attached hereto.

was filed on _____ as
 Application Serial No. _____
 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)	Priority Claimed
------------------------------	------------------

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520
 Address all correspondence to _____

EZRA SUTTON, P.A.

Plaza 9, 900 Route 9

Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Dr. Edward L. TOBINICK
 Inventor's signature X Date February 21, 1999
 Residence Los Angeles, California 90024-6903 Citizenship United States of America
 Post Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Full name of second joint inventor, if any ARTHUR JEROME TOBINICK
 Second Inventor's signature Arthur Jerome Tobinick Date February 21, 1999
 Residence Los Angeles, California 90024-6903 Citizenship USA
 Post Office Address 100 UCLA MEDICAL PLAZA, SUITE 205
Los Angeles, California 90024-6903

Applicant or Patentee: Dr. Edward L. TOBINICK / *Edward L. ToBINICK* Attorney's
Serial or Patent No.: _____ Docket No.:
Filed or Issued: _____ TOBINICK 3.0-007
Title: TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE

INDEPENDENT INVENTOR STATEMENT OF GEOLOGICAL DISORDERS
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.2(f) AND 1.27(b)) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark office with regard to the invention entitled TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

described in:
 the specification filed herewith
 Application Serial No. _____, filed _____
 Patent No. _____, issued _____.

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[X] no such person, concern, or organization
[] persons, concerns, or organizations listed below*

FULL NAME _____
ADDRESS _____

INDIVIDUAL **SMALL BUSINESS CONCERN** **NONPROFIT ORGANIZATION**

FULL NAME _____
ADDRESS _____

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dr. Edward L. TOBINICK ARTHUR JEROME TOBINICK
NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR
Edward L. Tobinick Arthur Jerome Tobinick
Signature of Inventor Signature of Inventor Signature of Inventor
X Feb. 21, 1999 Feb. 21, 1999
Date Date Date

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/256,388	02/24/99	514	1614	3.0-007

APPLICANT

EDWARD L. TOBINICK, LOS ANGELES, CA.

CONTINUING DOMESTIC DATA***

VERIFIED

371 (NAT'L STAGE) DATA***

VERIFIED

FOREIGN APPLICATIONS***

VERIFIED

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 03/15/99 ** SMALL ENTITY **

Foreign Priority claimed 35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY CA	SHEETS DRAWING 0	TOTAL CLAIMS 24	INDEPENDENT CLAIMS 1
Verified and Acknowledged Examiner's Initials _____	Initials _____				

ADDRESS

EZRA SUTTON
PLAZA 9 ROUTE 9
WOODBRIDGE NJ 07095

TITLE

TUMOR NECROSIS FACTORS ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

FILING FEE RECEIVED \$416	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK

3.0-007

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT, the specification of which

OF NEUROLOGICAL DISORDERS

(check one) is attached hereto.

was filed on _____ as
Application Serial No. _____
and was amended on _____ (if applicable).

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(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
_____	_____	_____

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
_____	_____	_____

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770

Address all telephone calls to _____ at telephone no. (732) 634-3520.

Address all correspondence to _____

EZRA SUTTON, P.A.

Plaza 9, 900 Route 9

Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Dr. Edward L. TOBINICK

Inventor's signature E.L. Tobinick Date February 21, 1999

Residence Los Angeles, California 90024-6903 Citizenship United States of America

Post Office Address 100 UCLA Medical Plaza, Suite 205

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Full name of second joint inventor, if any ARTHUR JEROME TOBINICK

Second Inventor's signature Arthur Jerome Tobinick Date February 21, 1999

Residence Los Angeles, California 90024-6903 Citizenship USA

Post Office Address 100 UCLA Medical Plaza, Suite 205

Los Angeles, California 90024-6903

TUMOR NECROSIS FACTOR ANTAGONISTS FOR
THE TREATMENT OF NEUROLOGICAL DISORDERS

FIELD OF THE INVENTION

5 The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; or autoimmune neurological disorders. More particularly, the TNF antagonists or TNF blockers are used in a new treatment of these disorders by
10 inhibiting the action of TNF in the cells of the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these neurological conditions.

BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease, immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmacologic agents, which are often not completely successful.

These neurological conditions include acute spinal cord trauma, spinal cord compression, spinal cord hematoma, cord contusion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic nerve compression,



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/256,388	02/24/99	TOBINICK	E 3.0-007

EZRA SUTTON
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 WOODBRIDGE NJ 07095

HM12/0927

EXAMINER

JARVIS, W

ART UNIT	PAPER NUMBER
	1614

DATE MAILED: 09/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Notice of Abandonment

Application No. 09/256,388

Tobinick

Examiner

William R. A. Jarvis

Group Art Unit

1614

This application is abandoned in view of:

applicant's failure to timely file a proper response to the Office letter mailed on _____.

A response (with a Certificate of Mailing or Transmission of _____) was received on _____, which is after the expiration of the period for response (including a total extension of time of _____ month(s)) which expired on _____.

A proposed response was received on _____, but it does not constitute a proper response to the final rejection.
(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC)).

No response has been received.

applicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date of the Notice of Allowance.

The issue fee (with a Certificate of Mailing or Transmission of _____) was received on _____.

The submitted issue fee of \$ _____ is insufficient. The issue fee required by 37 CFR 1.18 is \$ _____.

The issue fee has not been received.

applicant's failure to timely file new formal drawings as required in the Notice of Allowability.

Proposed new formal drawings (with a Certificate of Mailing or Transmission of _____) were received on _____.

The proposed new formal drawings filed _____ are not acceptable.

No proposed new formal drawings have been received.

the express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on _____.

the letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

the letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

the decision by the Board of Patent Appeals and Interferences rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

the reason(s) below:


WILLIAM R. A. JARVIS
PRIMARY EXAMINER
ART UNIT 1614

EZRA SUTTON*
OF COUNSEL
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Date

9/16/99

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703-308-7924

FROM: _____

EZRA SUTTON

FAX NO. _____

1-732-634-3511

PHONE: 1-732-634-3520

TOTAL NUMBER
OF PAGES: _____

1

Re: S.N. 09/256, 388

Applicant hereby abandons the
above-identified application in
favor of Appl. S.N. 09/275, 070,
which has been allowed by
Examiner Jarvis.

Joe Sutton
REG. NO. 25,170